REMARKS

Applicants cancelled claims 92, 94-103, 111, and 117. Claims 74, 76-84, 86-91, 104, 106-110, 112-116, 118, and 120-139 are presented for examination.

Claim rejections – 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 74-139 under 35 U.S.C. § 112, first paragraph as failing to meet the enablement requirement.[1]

As a basis for the rejection, the Examiner states that:

> [T]he specification does not indicate which polyamides listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various *mechanical property minima* (equivalently, minimum values) listed on pages 2-5 of the specification and claimed. (Office Action, page 3, emphasis added).

It appears that the Examiner requires that Applicants specify which polyamides satisfy the various mechanical property minima for the ranges appearing in the claims in order to overcome the enablement reject. We respectfully submit that this requirement is contrary to both Patent Office practice and Federal Circuit precedent.

In order to make an enablement rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). MPEP § 2164.08 states that:

> All questions of enablement are evaluated against the claimed subject matter.... The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually. (emphasis in original).

[1] Applicants cancelled claims 75, 85, 93, 105, and 119 in a previous amendment and cancelled claims 92, 94-103, 111 and 117 in the current amendment, so the rejection of these claims should be withdrawn.

By focusing on only mechanical property minima, i.e. the endpoints of the claimed ranges of mechanical properties, the Examiner has failed to consider the claims as a whole. The Examiner has not met his burden by providing a reasonable explanation as to why the scope of protection provided by a claim *as a whole* is not adequately enabled by the disclosure. Thus, the enablement rejection is improper.

The Federal Circuit has repeatedly held that the proper standard for enablement is that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright,* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. MPEP § 2164.08.

For example, "[w]hen a range is claimed, there must be *reasonable enablement* of the scope of the range." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003). The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *See, e.g., In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As discussed in detail below, Applicants have provided sufficient guidance to reasonably enable the scope of the claimed ranges. Applicants should not be subject to an additional requirement to disclose specific information related to the practice of the invention at a particular point chosen by the Examiner.

To determine whether a disclosure reasonably enables one skilled in the art to practice the full scope of the claimed invention without undue experimentation, MPEP § 2164.01(a) directs the Examiner to consider a number of factors, including those laid out by the Federal Circuit in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Two important factors in a so-called *Wands* analysis are the amount of guidance in practicing the claimed invention and the presence of working examples in Applicants' specification.

Applicants' specification provides a substantial amount of guidance in practicing the claimed invention. While claims 74, 76-84, 86-91,104, 106-110, 112-116, 118, and 120-139 are directed to articles without limitation to their methods of manufacture, the application provides a

detailed description of exemplary processes that can be used in the preparation of the devices covered by these claims. (*See, e.g.,* application at pages 17-24, Figs. 4A-4E and 5A-5E.) General features of such exemplary processes are disclosed at pages 17-21 with reference to Figs. 3A-3E and at pages 21-24 with reference to Figs. 5A-5E. The application discloses, for example, information relating to: the manner in which process temperature, longitudinal strain and internal pressure can depend upon each other (*see, e.g.,* id., at page 18-19); appropriate process temperatures (*see, e.g.,* id., at 19-22); appropriate longitudinal strains (*see, e.g.,* id., at 20-21); and appropriate internal pressures (*see, e.g.,* id., at 21-22).

Moreover, the specification provides a number of very detailed working examples of articles with mechanical properties falling within the claimed ranges. For example, with respect to a polyamide having a tensile strength of at least about 21,000 pounds, in example H (application at page 28), an extruded sheath of Vestamid L2101 F Nylon 12 (a polyamide) was longitudinally stretched and blown under a longitudinal strain of 220% and an internal pressure of 142 psi. During longitudinal stretch blowing, the sheath material passed through an 18 inch oven at a temperature of about 63°C over a period of about 8.9 seconds. A 304L stainless steel hypotube having an outer diameter of about 0.0264 inch and an inner diameter of about 0.0200 inch was inserted inside the longitudinally stretched and blown sheath, and the sheath was bonded to the hypotube by heating to a temperature of about 113°C for at least about 30 minutes. Five specimens sample H were tested, and the average tensile strength of specimens of sample H was 31,659 psi (application at page 26).

Further, regarding a polyamide having a hoop stress of at least about 3300 psi, in Example H, the average hoop stress of specimens is calculated to be 5,115 psi, using the outer and inner diameter values listed in Table II (*id.*) and the definition of hoop stress provided at page 11, lines 7 and 8 of the application.

In addition, with respect to a polyamide having a post buckle fracture tensile strength of at least about 6,500 psi, the application discloses numerous specific relevant examples. For example, in Example C (application at page 26), an extruded sheath of Vestamid L2101 F Nylon 12 (a polyamide) was longitudinally stretch-blown under a longitudinal strain of 220 % and an

internal pressure of 208 psi. During longitudinal stretch-blowing, the sheath material passed through an 18 inch oven at a temperature of about 63°C over a period of about 8.9 seconds. A 304L stainless steel hypotube was inserted inside the longitudinally stretched and blown sheath, and the sheath was bonded to the hypotube by heating to a temperature of about 113°C for at least 30 minutes. The specimens of example C have a post buckle tensile strength of 13,642 psi (application at page 25-26, Table I), which is greater than 6500 psi as claimed. Further, the application discloses detailed processes for making examples D including a polyamide, Example E including a polyamide copolymer, Example F including a polyamide copolymer, and G including a polyamide copolymer, all of which have a post buckle average tensile strength of the hypotube sheaths greater than 6500 psi as claimed.

Applicants submit that this information would certainly allow one skilled in the art to practice the invention without undue experimentation.

Further, Applicants note that the mere fact that the specification describes a number of possible materials which can be used to make the claimed article does not necessarily mean that undue experimentation is required. For example, in *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.* 70 F.2d 1569, 1576-1577 (Fed. Cir. 1984), the Federal Circuit held that a district court did not err in finding a patent specification enabling even though it listed starting elements that could form *thousands* of end products, some of which may not be operative. The court noted that the fact "[t]hat some experimentation is necessary [in choosing the starting elements] does not preclude enablement..." because no undue experimentation was required to practice the invention. *See id.*

Finally, the Examiner objects to the use of the phrase "load at break ratio," in several claims. Applicants have cancelled all claims in which this phrase appears, thereby obviating the issue.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

35 U.S.C. §102(b) Rejections

The Examiner rejected claims 74, 76-78, 80-82, 104, 106-109, 112-115, 118, 120-123 and 125-128 under 35 U.S.C. §102(b) as being anticipated by Pinchuk et. al., U.S. Pat. No. 6,110,142 ("Pinchuk"), and the Examiner rejected claims 84, 86, 88, 89, and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian, U.S. Pat. No. 5,306,246 ("Sahatjian").

Applicants' remind the Examiner that an Applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). *See In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Where an explicit definition for a claim term is provided by an Applicant, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053* (Fed. Cir. 1987); *see also* MPEP § 2131. Further, anticipation of a claimed product cannot be predicated on mere conjecture as to the characteristics of a prior art product. *See W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, ___ (Fed.Cir.1983); *see, also, Ex Parte Standish*, Appeal No. 1987-0178 (BPAI 1988) (Examiner's finding of anticipation improper when because whether a claimed feature was shown in a prior art reference was "not entirely clear.")

I. Pinchuk

The Examiner rejected claims 74, 76-78, 80-82, 104, 106-109, 112-115, 118, 120-123 and 125-128 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.

A. Tensile Strength of at least about 21,000 PSI

Claims 74, 76-78, 80-82, 109, 115, 123 and 128 cover articles including a polyamide having a tensile strength of at least about 21,000 psi. Pinchuk does not disclose such articles. Rather, Pinchuk discloses balloon catheters in which the balloon-portion is reported to:

> have a *calculated tensile strength* of between about 15,000 and about 35,000 psi and above, preferably between about 20,000 and about 32,000 psi. (Pinchuk col. 11, lines 13-21, emphasis added).

It is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the tensile strength defined in Applicants' specification at, for example, page 10, line 30 to page 11, line 2. As a result, for at least this reason, the Examiner has not met his burden in establishing that Pinchuk anticipates claims 74, 76-78, 80-82, 109, 115, 123 and 128.

B. Hoop Stress Ratio of at least about 1.25

Claims 104, 106-109 and 112-115 cover articles including a polyamide having a hoop stress ratio of at least about 1.25. Pinchuk does not disclose such articles. Instead, Pinchuk discloses balloon catheters where:

> [t]he relationship between balloon tailorability and hoop expansion ratio is illustrated in FIG. 7. Three non-sterilized nylon balloons having different *hoop expansion ratios* were tested at 37.degree. C., the expansion being to burst. A relatively high *hoop expansion ratio* of 4.9 (curve N) gave a balloon distention (safely short of burst) of about 7 percent. A 3.7 *hoop expansion ratio* (curve O) gave a balloon distention of about 23 percent, while a 3.3 *hoop expansion ratio* (curve P) gave a balloon distention of about 36 percent. (Pinchuk col. 13, lines 14-19, emphasis added)

Pinchuk defines *hoop expansion ratio* as the "mean balloon diameter divided by mean as-extruded tubing or parison diameter." (Pinchuk, col. 11, lines 65-67.) In contrast, Applicants determine *hoop stress* ratio "by dividing the *hoop stress* of the material as a tube shaped ... component ...by the *hoop stress* of the material before being longitudinally or radially stretch blown." (application, p. 24, lines 20-25). Obviously, Pinchuk's "hoop expansion ratio" is not the same as the "hoop stress ratio" required by claims 104, 106-109 and 112-115. Thus, for at least this reason, the Examiner has not met his burden in establishing that Pinchuk anticipates these claims.

C. Post Buckle Fracture Tensile Strength of at least about 6500 PSI

Claims 118, 120-123 and 125-128 cover articles including a polyamide having a post buckle fracture tensile strength of at least about 6500 psi. Pinchuk does not disclose such articles. To the contrary, Pinchuk discloses balloon catheters in which the balloon-portion is reported to:

> have a *calculated tensile strength* of between about 15,000 and about 35,000 psi and above, preferably between about 20,000 and about 32,000 psi. (Pinchuk col. 11, lines 17-21, emphasis added.)

It is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the post buckle fracture tensile strength defined in Applicants' specification at, for example, page 12, lines 4-27. Accordingly, for at least this reason, the Examiner has not met his burden in establishing that Pinchuk anticipates claims 118, 120-123 and 125-128.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 74, 76-78, 80-82, 104, 106-109, 112-115, 118, 120-123 and 125-128 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.

II. Sahatjian Rejection

The Examiner rejected claims 84, 86, 88, 89, and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian.

Claims 84, 86, 88, 89 and 91 cover articles including a polyamide having a hoop stress of at least about 3300 psi.

Sahatjian does not disclose such articles. Rather, Sahatjian discloses blends of polyolefins (e.g., polyethylene, polypropylene, polybutylene and copolymers thereof) and polyesters for dilatation balloons, and discloses suitable polyolefins and polyesters for forming blends. (*See, e.g.,* Sahatjian, col. 3, lines 4-7, lines 14-15, and lines 37-43). Sahatjian does disclose, in particular embodiments, balloons produced using known methods for blending incompatible polymers (e.g., polyesters and polyolefins) using condensation polymers. (*See, e.g., id.*, col. 3, lines 48-63.) In some cases, the condensate polymer may be a polyamide. (*See,*

e.g., id.) However, Sahatjian does not provide any information about the hoop stress characteristics of balloons produced by his blending method. Instead, Sahatjian provides a lengthy discussion and numerous examples (including hoop stress characteristics) for balloons made of materials *other than polyamides*. (*See, e.g,*. Sahatjian, Examples I and II, Table 1, and FIG. 4.) Thus, contrary to the Examiner's assertion, Sahatjian does not disclose a balloon *which includes a polyamide* (in the form of a condensate polymer or otherwise) with a hoop stress greater than about 36,000 psi. Applicants therefore request reconsideration and withdrawal of the rejection of claims 84, 86, 88, 89, and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian.

35 U.S.C. §103(a) Rejection

Pinchuk in view of Sahatjian

The Examiner rejected claims 79, 83, 110, 116, 124, and 129 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Sahatjian.

But, there is not suggestion to combine these references. Pinchuk discloses balloon catheters made out of polyamides. (Pinchuk, col. 10, lines 30-31). According to Pinchuk, there are advantageous properties of polyamides used in this fashion. (*See, e.g., id.,* col. 10 lines 30-61). In contrast, Sahatjian teaches the use of a balloon "composed predominantly of a blend of crystallizeable resin and [an] ... additive polymer, e.g., polyolefin, that interrupts the crystalline network of the crystalline resin in the final product. " (Sahatjian, abstract). Sahatjian further states that:

> [i]n particular embodiments, the balloon is composed of a minor amount of heterogeneous, preblended, polyolefin (e.g. polyethylene) and a polyester (e.g. PET); the preblend is then blended with a relatively high molecular weight PET.... Suitable polyolefins and polyesters for forming the preblend and methods for blending incompatible polymers are known and are discussed in U.S. Pat. No. 4,444,817 entitled "Process for Making Laminar Articles of Polyolefins and Condensation Polymer", by Subramanian, the entire contents of which are hereby incorporated by reference. ...*The condensation polymers may be a polyamide*, or polyester such as PET or polycarbonates. (Id., col. 3, lines 48-64).

However, as described in detail in the Subramanian patent, U.S. Pat. No. 4,444,817, a condensate polyamide in a polyolefin/polyester blend serves only to allow the blending of the incompatible polyolefin and polyester (col 2, lines 25-42). The blend is composed primarily of the polyolefin and polyester and would not, in general, exhibit the same properties of the polyamide standing alone (*see, e.g.*, col. 5, lines 7-21). One skilled in the art would have recognized that the polyolefin/polyester blend balloon described in Sahatjian would not, in general, exhibit the same advantageous properties as the polyamide balloons described in Pinchuk, and therefore would be incompatible with the device of Pinchuk. Thus a person skilled in the art at the time of the invention would not have combined the balloon of Sahatjian with the device of Pinchuk.

Even if the combination of Pinchuk and Sahatjian were proper, the combined references still do not disclose each and every limitation appearing in claims 79, 83, 110, 116, 124, and 129

Claims 79 and 83 cover articles including a polyamide having a tensile strength of at least about 21,000 psi. As discussed above, the Examiner has not demonstrated that Pinchuk recites this limitation. Sahatjian makes no mention of tensile strength values, and therefore does not cure this difficulty. Thus Applicants submit that claims 79 and 83 patentably distinguish any combination of Pinchuk and Sahatjian.

Claims 110 and 116 cover articles including a polyamide having a hoop stress ratio of at least about 1.25. As discussed above, the Examiner has not demonstrated that Pinchuk recites this limitation. Sahatjian makes no mention of hoop stress ratio values, and therefore does not cure this infirmity. Thus Applicants submit that claims 110 and 116 patentably distinguish any combination of Pinchuk and Sahatjian.

Claims 124 and 129 cover articles including a polyamide having a post buckle fracture tensile strength of at least about 6500 psi. As discussed above, the Examiner has not demonstrated that Pinchuk recites this limitation. Sahatjian makes no mention of post buckle fracture tensile strength values, and therefore does not cure this difficulty. Thus Applicants submit that claims 124 and 129 patentably distinguish any combination of Pinchuk and Sahatjian.

Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 79, 83, 110, 116, 124, and 129 under 35 U.S.C. §103(a).

Sahatjian in light of Pinchuk

The Examiner rejected claims 87 and 90 under 35 U.S.C. §103(a) as being unpatentable over Sahatjian in light of Pinchuk.

Applicants do not concede that the suggested combination of Sahatjian and Pinchuk is proper. However, even if the combination of Pinchuk and Sahatjian were proper, the combined references still do not disclose each and every limitation appearing in claims 87 and 90.

Claims 87 and 90 cover articles including a polyamide having a hoop stress of at least about 3300 psi. As discussed above, the Examiner has not demonstrated that Sahatjian discloses an article including a region that comprises a polyamide having a hoop stress of at least about 3300 psi, as required by the claims. Further, the Examiner, at page 6 of the Office Action, states that Pinchuk fails to teach a balloon that has a hoop stress of at least about 3300 psi. Thus, Applicants submit that claims 87 and 90 patentably distinguish any combination of Pinchuk and Sahatjian.

Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 87 and 90 under 35 U.S.C. §103(a).

Conclusion

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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